AMERICAN PODIATRIC MEDICAL ASSOCIATION, INC.

August 31, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

RE: CMS-1501-P
Comments on Medicare Program; Medicare Program; Changes to the Hospital Outpatient
Prospective Payment System and Calendar Year 2006 Payment Rates – Drugs, Biologicals, and Radiopharmaceuticals Non Pass-throughs (70 Fed. Reg. 42674, July 25, 2005)

Dear Dr. McClellan:

The American Podiatric Medical Association (APMA) is concerned with the provision of the proposed rule, "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" that relates to the payment rates for the wound-healing products Apligraf [C1305] and Dermagraft [C9201]. We believe that an error has been made and we respectfully request that the payment rates for Apligraf and Dermagraft be corrected in the final rule.

Apligraf and Dermagraft have been paid in the hospital outpatient prospective payment system as specified covered outpatient drugs and we believe that they should continue to be paid in 2006 similar to other such drugs.

In the proposed Hospital Outpatient Prospective Payment System (HOPPS) Rule for calendar year 2006, the Centers for Medicare & Medicaid Services (CMS) proposes to pay specified covered outpatient drugs at average sales price [ASP] plus six percent for the acquisition cost of the drug. The rule proposes to pay a pharmacy overhead charge of an additional two percent, which results in a total payment for specified covered outpatient drugs of ASP plus eight percent.

In 2002, both Apligraf and Dermagraft were paid as a biological under the pass through list. Following the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, both products have been paid for as sole-source biologicals in 2004 and in 2005 under the specified covered outpatient drug provision.

9312 Old Georgetown Road Bethesda, Maryland 20814-1621
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Both products were included in the General Accountability Office [GAO] survey of acquisition costs for specified covered outpatient drugs dated June 30, 2005 [GAO-05-581R]. The GAO report included the relevant ASP rates for each product. However, in the proposed rule both Dermagraft and Apligraf were incorrectly paid based on rates derived from claims data instead of payment at ASP plus eight percent. Accordingly, both products experienced a significant decrease in payment:

Apligraf – 2005 outpatient rate $1,130.88; 2006 proposed outpatient rate $766.84
Dermagraft – 2005 outpatient rate $529.54; 2006 proposed outpatient rate $368.32

We believe that there may have been some confusion in addressing these products for the proposed rule because the products are reimbursed in the physician's office under codes with different descriptors. In the physician office setting, Apligraf and Dermagraft have been paid based on the ASP plus six percent methodology under J7340 [*Metabolic active Dermal/Epidermal tissue*] and J7342 [*Metabolically active Dermal tissue*] respectively.

Apligraf and Dermagraft are unique living human tissue substitutes for the treatment of chronic ulcers. Our members use these products in treating Medicare beneficiaries with diabetes, as well as in the treatment of thousands of other patients who suffer from chronic foot and leg ulcers. We believe that these products have been beneficial in helping to preserve limbs, which has resulted in a better quality of life for these individuals. Without products such as Dermagraft and Apligraf, many patients would have undergone limb amputations.

If these products are not appropriately reimbursed, we believe that a Medicare beneficiary's access to the standard of care wound treatment may be compromised. In an effort to address this issue in the short term, APMA, along with other organizations, has requested a meeting with Mr. Herb Kuhn. It is our hope and expectation that this issue may be effectively addressed prior to publication of the CMS final rule.

If you have questions concerning our comments, please contact Dr. Nancy L. Parsley, Director of Health Policy and Practice, at (301) 581-9233.

Sincerely,

Harold B. Glickman DPM

Harold B. Glickman, DPM
President

62-O
(10)

1501-P

CMS-[redacted]-P-711 **Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006**

Submitter : **Ms. Deanna Galloway** **Date & Time:** **09/08/2005**

Organization : **Curative Health Services/Lourdes Wound Care Center**

Category : **Other Health Care Provider**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1502-P-711-Attach-1.DOC

09/08/05

Mr. Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20201

ATTN: FILE CODE CMS-1501-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates -- Drugs, Biologicals, and Radiopharmaceuticals Non Pass-throughs

Dear Mr. Kuhn:

Deanna Galloway is submitting this public comment to bring to your attention an error in the proposed rule, CMS-1501-P, "Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates" relating to the payment rates for the wound-healing products Apligraf (C1305) and Dermagraft (C9201).

These products have been paid in the hospital outpatient prospective payment system as specified covered outpatient drugs and should continue to be paid in 2006 similar to other such drugs. Patient access to these important products is jeopardized by the payment rates in the proposed rule. We respectfully request that the payment rates for Apligraf and Dermagraft be corrected in the final rule.

Apligraf and Dermagraft are unique living human tissue substitutes for the treatment of chronic ulcers. These products have preserved and improved the quality of life of thousands of diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Many of these patients would have had to undergo limb amputations without the benefits of Apligraf and Dermagraft.

As you know, in the proposed Hospital Outpatient Rule for calendar year 2006 the Centers for Medicare and Medicaid Services proposed to pay specified covered outpatient drugs at average sales price (ASP) plus six percent for the acquisition cost of the drug. The rule proposes to pay a pharmacy overhead charge of an additional two percent which results in a total payment for specified covered outpatient drugs of ASP plus eight percent.

In 2002 both Apligraf and Dermagraft were paid as a biological under the pass through list. Following the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, both products have been paid for as sole-source biologicals in 2004 and in 2005 under the specified covered outpatient drug provision. Both products were included in the General Accountability Office (GAO) survey of acquisition costs for specified covered outpatient drugs dated June 30, 2005 (GAO-05-581R). The GAO report included the relevant ASP rates for each product.

However, in the proposed rule both Apligraf and Dermagraft would be incorrectly paid based on rates derived from claims data in stead of payment at ASP plus eight percent. Accordingly, both products experienced a significant decrease in payment:

Apligraf -- 2005 outpatient rate $1,130.88; 2006 proposed outpatient rate $766.84

Dermagraft -- 2005 outpatient rate $529.54; 2006 proposed outpatient rate $368.32

There may have been some confusion in the proposed rule because the products are reimbursed in the physician's office under codes with different descriptors. In the physician office setting, Apligraf and Dermagraft have been paid based on the ASP + six percent methodology under J7340 (Metabolic active Dermal/Epidermal tissue) and J7342 (Metabolically active Dermal tissue) respectively.

Thank you for your attention to this issue and we look forward to working with you to correct the issue in the final rule.

Sincerely,

Deanna Galloway, Program Director
Curative Health Services
Lourdes Wound Care Center
Paducah, KY

63-O
(37)

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September 7, 2005

Mark B. McClellen, M.D., PhD
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS – 150[illegible] – P
7500 Security Boulevard
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System And Calendar Year 2006 Payment Rates; Proposed Rule

File Code: CMS – 150[illegible] – P
Proposed Payments for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

Dear Mr. McClellen:

As a practicing physician treating patients with chronic wounds, I am very concerned with the proposed 2006 Medicare Hospital Outpatient payment for Dermagraft [C 9201] and Apligraf [C 1305].

For this reason, I am submitting comments in response to the Centers for Medicare and Medicaid Services [CMS Proposed Rule – Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule.

Apligraf and Dermagraft are distinctive living human tissue substitutes for the treatment of chronic wounds. These products have improved the quality of life of thousands of diabetics and Medicare beneficiaries who suffer from chronic wounds. Many of these patients would have had to undergo amputations without the benefits of Dermagraft and Apligraf.

Practicing physicians, like me treating a variety of chronic wounds have been able to use these living tissue substitutes to successfully treat Medicare beneficiaries when other treatment modalities have been unable to heal these difficult wounds.

As you may know, since 2002 both Apligraf and Dermagraft were paid as biologics under the Hospital Outpatient transitional pass through program. Both products also have been paid for as sole-source biologics in 2004 and 2005 with the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

In the proposed 2006 Medicare Hospital Outpatient Rule, CMS plans to reimburse covered outpatient drugs at average sales price [ASP] + six percent for the acquisition cost of the drug.

For some reason however, in the proposed rule both Apligraf and Dermagraft were incorrectly paid based on 2004 claims data instead of payment based on ASP. Because of the claims data calculation, both products experienced a significant decrease in payment which is unacceptable for purchasing hospitals:

Dermagraft	**2005 hospital outpatient payment = $ 529.54** **2006 proposed hospital outpatient payment = $ 368.32**
Apligraf	**2005 hospital outpatient payment = $1,130.88** **2006 proposed hospital outpatient payment = $ 766.84**

Dermagraft and Apligraf have been reimbursed in the hospital outpatient setting as covered outpatient drugs and this payment methodology should continue in 2006 like other covered outpatient drugs. Without this, Medicare beneficiary access to these advance treatment options is jeopardized by the payment rates in the 2006 Medicare proposed rule.

I request that the proposed 2006 Medicare hospital outpatient reimbursement for Apligraf and Dermagraft be corrected in the final rule that will be issued later this year.

Thank you for your prompt attention and correction of this 2006 payment issue.

Best regards,

Dr. William B. Turner, DPM, CWS

cc: Herb Kuhn
Director, Center for Medicare Management
Centers for Medicare and Medicaid Services
200 Independence Avenue
Washington, DC 20201

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220 Young Avenue #50
Cocoa Beach, FL 32931

September 4, 2005

Cryo

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: CMS-1501-P: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates for APC 674: Cryosurgery of the Prostate

Dear Dr. McClellan:

I am responding to a notice in the July Federal Register in order to urge that consideration be given to increasing the proposed payment for APC 674 reflecting a hospital's actual cost for performing prostate cryosurgery.

I was diagnosed with prostate cancer in 1993 and I had external radiation treatments which reduced my PSA from 15.0 down to 1.5. The readings stayed low for about 7 years and then started to rise slowly to a reading of 20.0 in 2004.

I had heard about cryosurgery from a friend who had the procedure done and was doing well. In October 2004 I decided to have Dr. Steven Hulecki in Sebastian, FL perform the surgery. It was minimally invasive and the side effects were slight. My recovery time was quick and I spent only one night in the hospital. Now, after one year my PSA remains at 0.00 and I feel fine.

I want to reiterate how successful the cryosurgery was for me. I hope you can make the procedure available to all who have a similar condition. Thank you.

Sincerely,

William V. Chapp

William V. Chapp

Mary Robinson

From: Hayes, Yolanda K. (CMS/OSORA) [Yolanda.Hayes@cms.hhs.gov]
Sent: Saturday, September 17, 2005 10:37 AM
To: Mary Robinson
Subject: CMS-1501-P Face sheets

Will send attachments separate. Could you leave message on my phone to let me know it you received them? I will check my messages Monday.

Behar & Kalman
ATTORNEYS AT LAW
SIX BEACON STREET
BOSTON, MASSACHUSETTS 02108-3802
PHONE (617) 227-7660
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EDWARD D. KALMAN
ekalman@beharkalman.com

September 8, 2005

Via Overnight Mail

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1501–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Comments on Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates – Evaluation and Management Services

Dear Dr. McClellan:

I am pleased to provide these comments on behalf of the Yale New Haven Hospital ("YNHH" or the "Hospital") with regards to the "Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule" published on July 25, 2005 at 70 *Fed. Reg.* 42674 *et seq.* YNHH is a 944-bed tertiary care hospital located in New Haven, Connecticut which serves as a teaching hospital for the Yale School of Medicine. The Hospital is a major provider of health care services within the State of Connecticut. YNHH also provides comprehensive tertiary care services to patients referred to it from throughout the New England region as well as from foreign countries. The Hospital provides over 250,000 days of inpatient care and almost a half a million outpatient visits per year. YNHH's outpatient activities include services to over 100,000 patients who seek care on an emergency basis from YNHH emergency department facilities.

BACKGROUND AND SUMMARY OF COMMENTS PAYMENT EVALUATION AND MANAGEMENT ("E/M") SERVICES

These comments respond to proposals as to the manner in which the Medicare program uses *Current Procedural Terminology* ("CPT") code definitions which have been adopted by the American Medical Association ("AMA") as a basis to classify patients who receive emergency department services for payment purposes under the Medicare outpatient prospective payment

system ("OPPS").[1] In July of 2004, YNHH established a provider-based component of its emergency department, known as the YNHH Shoreline emergency department facility ('the Shoreline facility"). The Shoreline facility is fully integrated into the emergency department of YNHH. It operates in Guilford, Connecticut which is located approximately 15 miles from the YNHH main campus in New Haven, Connecticut. The Shoreline facility operates on less than a 24-hour basis, as do provider-based emergency department facilities established by other hospitals within the State of Connecticut. These provider-based hospital emergency department satellite facilities form vital components of the emergency services network which has been authorized by the Public Health Department for the State of Connecticut. In accordance with this mandate, the Shoreline facility functions as an integral part of YNHH's full-time, 24-hour, emergency room department. In October of last year, the Centers for Medicare and Medicaid Services ("CMS") advised YNHH that CPT code definitions require that emergency departments operate on a full-time, 24-hour basis as a prerequisite to payment at emergency department rates under OPPS. YNHH was advised to bill for the services it provides at the Shoreline facility at outpatient clinic rates of payment. Clinic payment rates can be over $100 lower per visit than emergency department rates of payment. Clinic rates do not reflect the emergency department capital, technology, skilled labor or specialized procedure costs and other medical resources provided by emergency departments and which are provided and used by Medicare beneficiaries at the Shoreline facility. YNHH disagrees with this decision and notes that CMS (as well as its predecessor the Health Care Financing Administration ("HCFA") has not, in the past, precluded payment at emergency department rates for services provided to Medicare beneficiaries in a provider-based component of a full-time emergency department like the Shoreline facility which operates on a part-time basis. YNHH requests that, in the absence of explicit data-driven analysis and policymaking which would justify a different level of payment, the evaluation and management codes proposed in the FY 2006 OPPS rule be clarified to allow existing hospital-based satellite emergency facilities such as the YNHH Shoreline facility to submit bills to the Medicare program at emergency department rates. A summary of YNNH's comments are:

1. Prior to the October 1, 2002 implementation date of OPPS, the Medicare program reimbursed services provided by hospital provider-based emergency department facilities on a reasonable-cost basis. As such, medical resource use and related costs of care received by Medicare beneficiaries was fully reflected in Medicare payment rates.

2. At all times before and after adoption of the OPPS, CMS, as well as its predecessor HCFA, has instructed hospitals which have established less than full-time hospital, provider-based emergency department satellite facilities that they must meet all Medicare program requirements for emergency departments, which *per force* requires these facilities to provide hospital level emergency department medical resources and to make a higher intensity of care and medical resources available to Medicare beneficiaries than is customarily provided on an outpatient clinic basis.

3. The assignment of services to Ambulatory Payment Classifications ("APCs") is based on an analysis of charges assigned to various cost reporting cost centers. The costs and charges related to less than full-time, provider-based satellite facilities are collected within the

[1] These comments, *inter alia*, relate to the application of CPT Codes 99281 through 99285 which pertain to emergency department visits and are contained at 70 *Fed. Reg.* 42903 (July 25, 2005).

emergency department cost center on Medicare cost reports and are not reflected in any way in the outpatient clinic cost centers used to establish rates of payment for hospital clinic visits under OPPS.

4. Section 1833(t)(2)(A) of the Social Security Act requires that the OPPS classification system be composed of groups of services, so that services within each group are comparable both clinically and with respect to the medical resources used to provide patient care. Medical resources required and used by beneficiaries who access care at the Shoreline facility are different in terms of equipment as well as the scope, technology and intensity of services than those that are provided on an outpatient clinic basis. The Shoreline facility must, and does, as a matter of law and sound health care practice, provide the same types of services that are provided by other emergency department facilities, regardless of their hours of operation. Additionally, the Shoreline facility's comprehensive emergency department resources and staff predictably are more intensive and hence more costly than some 24-hour emergency department facilities.

5. The Secretary has not engaged in a process of public notice and comment to change the policy which clearly existed prior to OPPS to reimburse services provided by hospital-based, less than full-time emergency department facilities like the Shoreline facility on the same basis as all emergency department facilities are reimbursed by the Medicare program. The Secretary consistently has instructed hospitals they must provide emergency department and not less intensive services in emergency facilities like Shoreline which operate on less than a 24-hour basis. CPT code definitions were never identified, in any rulemaking process, as changing Medicare pre-OPPS policy which recognizes facilities like the Shoreline facility as part of a hospital's emergency department for payment purposes. Indeed, to the contrary, and as discussed in Part III of these comments, the Secretary explicitly has recognized that CPT codes are not an appropriate basis to classify patients with respect to hospital facility use, including emergency department resource use for payment purposes. Medicare-Medicaid Conditions of Participation ("CoPs") and regulations promulgated under the Emergency Medical Treatment and Active Labor Act ("EMTALA") recognize hospital provider-based emergency facilities like the Shoreline facility as part of the emergency department of a hospital and hold them accountable to provide emergency and not clinic services.

Given the absence of formal rulemaking on this issue, and particularly, the frank acknowledgement that CPT codes are inadequate to define hospital resource use, CMS' recent direction to YNHH not to bill at emergency department rates is a departure from past policy which raises significant questions of law and policy. See Mercy Medical Skilled Nursing Facility v. Thompson *et al.*, Civil Action Nos. 99-2765, 01-2014, 02-2252, and 02-2253, (D.C. Cir. May 14, 2004), p.2, CCH Medicare-Medicaid Guide, ¶301,455 (Program Memorandum which departed from the Secretary's prior ten year policy of reimbursing in full all atypical service costs above the routine cost limit violated the Administrative Procedure Act because "it constitutes a change in the Secretary's definitive interpretation made without following the required notice-and-comment procedures.") The United States District Court for the District of Columbia noted it did not matter whether the policy was written. "Any significant alteration of that established practice requires notice and an opportunity for those affected to comment. To hold otherwise would grant agencies the power to reinterpret regulations at will so long as their prior interpretations, no matter how established, had not been written down." Id. at p.3. See

Tenet Healthsystem Hospitals, Inc. d/b/a St. Charles General Hospital and Tenet Healthsystem Hospitals, Inc. d/b/a Century City Hospital v. Shalala, Civil Action No. 97-3499, (E.D. La. Nov. 4, 1998), CCH Medicare-Medicaid Guide, ¶300,116 and cases cited (Broad deference is not appropriate where an agency's new interpretation of its regulations conflicts with a prior interpretation on which plaintiffs reasonably relied). See also Vencor, Inc. v. Shalala, 988 F. Supp. 1467 (N.D. Ga. Dec. 23, 1997), CCH Medicare-Medicaid Guide, ¶300,053 (Memorandum which set forth a geographic proximity requirement for hospitals and skilled nursing facilities operation under a written transfer agreement was unreasonable, arbitrary and capricious, where a geographic proximity requirement was not set forth in the statute or regulation and the new policy departed from prior longstanding policy and was adopted without notice and comment); Hospital Therapy Services of Georgia, Inc. v. Shalala, Civil Action No. 1:95-CV-2951-JOF, slip op. (N.D. Ga. Aug. 14, 1997), CCH Medicare-Medicaid Guide, ¶45,744 (the same Memorandum at issue in Vencor, supra, which imposed a geographic proximity requirement where the Medicare program's prior policy allowed reimbursement claims irrespective of the distance between the hospitals and skilled nursing facilities, was found to be unlawful because it was not in accordance with law, constituted unlawful rulemaking under the Administrative Procedure Act, and was vague, arbitrary and capricious). These cases stand for the well-established rule of administrative law that an agency such as CMS may not change its policy *sub silentio*. Roadway Express, Inc. v. NLRB, 647 F.2d. 415, 419 (Cir. 4 1981).

I. CMS' Payment Policy for Emergency Department Services Should be Consistent both with State Decisions to Authorize Hospital-Based Emergency Department Facilities as well as with CMS' Certification Policies.

CMS' payment policy should recognize that the State of Connecticut has organized its state-wide emergency services to include part-time, hospital based emergency departments. On December 6, 2002, the Office of Health Care Access ("OHCA")[2] of the State of Connecticut issued a Certificate of Need ("CON") to YNHH, authorizing YNHH to open the Shoreline facility. The Shoreline facility commenced operations in July of 2004. It operates 7 days per week but is open for less than 24 hours per day. Although Shoreline is not open 24 hours per day, as a matter of State law and the Medicare provider-based rules (42 C.F.R. §413.65), it is a fully-integrated component of YNHH's main emergency department which does operate 24 hours per day, 7 days per week. The operation of the satellite emergency department for less than 24 hours per day is consistent with local practice in the State of Connecticut, as prescribed by OHCA. In fact, the State of Connecticut has organized its hospital emergency network to include four, separate, hospital-based, emergency department satellite facilities which operate throughout the State on less than a 24 hour per day basis. It is important that Medicare policies harmonize with healthcare planning decisions by the State of Connecticut as to the manner in which it organizes its emergency services. Consistent underfunding of emergency department services, as is the case here, constitutes a *de facto* disapproval by the Medicare program of the State's decisions.

The Shoreline facility satisfies all state and federal requirements for operation and staffing as an emergency department, including provider-based requirements. The Shoreline

[2] OHCA has similarly authorized three additional hospital provider-based emergency department facilities which are currently in operation.

facility operates as an integral and inseparable component of YNHH's main campus emergency department. It operates under the direction and control of the main campus and meets applicable Medicare provider-based requirements and EMTALA requirements.

More specifically, the Shoreline facility operates as an extension of YNHH's main emergency department. The satellite is staffed by the same physicians and clinical personnel, including triage staff, as YNHH's main emergency department, and the administration and reporting relationships at the Shoreline facility are integrated with those of the main emergency department. In conjunction with YNHH's main emergency department, the medical direction and staffing of the satellite facility are by physicians who are credentialed to provide services as part of YNHH's medical staff, and who are either board-certified or board-eligible and experienced in emergency medicine.

II. CMS' Regulations and Policy Recognize Part-Time Emergency Hospital-Based Departments as Hospital Emergency Services and Not Clinic Services.

The final EMTALA rule indicates that emergency departments do not have to be open on a 24 hour per day, 7 day per week basis. In fact, CMS expressly rejected applying such a requirement to hospital emergency departments.

> We are not using the Arizona bill 24-hour or 8-hour requirements because we believe an objective measure based on outpatient visits for the treatment of emergency medical conditions will be easier to understand and implement and better reflects the operating patterns of some emergency departments, including those at small or rural hospitals, or both, that may not offer treatment for emergency medical conditions continuously on a 24-hour, 7 days a week basis. (The hospital CoPs governing emergency services of hospitals (§482.55) and CAHs (§485.618) do not require that emergency departments be operated continuously. Under some circumstances, such as local shortages of emergency care personnel or limited demand for emergency services, hospitals and CAHs may choose to open and staff their emergency departments on less than a 24-hour, 7 days a week basis.)
>
> 68 *Fed. Reg.* 53231 (September 9, 2003, effective November 10, 2003).

Accordingly, CMS declined to adopt a policy requiring an emergency department to be open 24 hours per day. Therefore, the definition of "dedicated emergency department" does not require that the emergency department be open 24 hours per day, 7 days per week.

> *Dedicated emergency department* means any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements:
>
> (1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department;

(2) It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or

(3) During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

42 C.F.R. §489.24(b).

Also, "[h]ospital with an emergency department" is simply defined to mean "a hospital with a dedicated emergency department as defined in this paragraph (b)." 42 C.F.R. §489.24(b).

Similarly, the Medicare CoPs for emergency services, which are referred to by CMS in the preamble to the final EMTALA rule, require that: "[t]he Hospital must meet the emergency needs of patients in accordance with acceptable standards of practice." 42 C.F.R. §482.55. There is no requirement that emergency services must be provided 24 hours per day, 7 days per week.

CMS considers the Shoreline facility to be a "dedicated emergency department" under EMTALA. As such it is required to satisfy all EMTALA requirements. Accordingly, Shoreline is required to provide medical resources and incur related costs which are not required of hospital outpatient departments or clinics. Since CMS treats the Shoreline facility as an emergency department both for certification purposes and for EMTALA purposes and requires it to comply with the related obligations of an emergency department, it also should treat it as such for payment purposes. Consistent with CMS' policy, as articulated in the final EMTALA rule, emergency services provided at a hospital-based, satellite facility emergency department that is not open 24 hours per day, that is authorized under state law and that meets Medicare certification requirements, should be coded and billed and reimbursed by CMS in the same manner as emergency services provided at the hospital's main emergency department.

III. CPT Codes Do Not Reflect Hospital Resource Use.

Section 1833(t)(2)(B) of the Social Security Act requires that the outpatient prospective payment system reflect and pay for hospital resource use. The Medicare program historically, both before and after the adoption of OPPS, has reimbursed services provided to program beneficiaries at part-time, provider-based, emergency departments at emergency department rates, not clinic rates. Otherwise stated, when OPPS became effective on October 1, 2002, the Secretary continued his past practice of recognizing part-time, hospital-based emergency department facilities as part of hospital emergency departments for payment purposes. At no time has the Secretary articulated a different policy except in the recent CMS letter to YNHH.

CMS' only reason for paying for emergency department services provided at a provider-based campus such as Shoreline at clinic rates is that the CPT codes established by the AMA for emergency department services reference that "[t]he facility must be available 24 hours a day." However, the CPT codes which were adopted by the AMA for physicians do not measure facility input and resources.

The Secretary, in the context of rulemaking, repeatedly has acknowledged that CPT codes are inadequate to define hospital resource use including hospital emergency department resource use. In its Medicare claims processing manual, CMS notes that the CPT codes it uses are "more descriptive of practitioner than of facility services." Medicare Claims Processing Manual (Pub. 100-4), Chapter 5.

In the proposed FY 2006 outpatient rule the Secretary stated that:

> In the November 15, 2004 final rule with comment period (69 *FR* 65838), we noted our primary concerns and direction for developing the proposed coding guidelines for emergency department and clinic visits.

70 *Fed. Reg.* 42740 (July 25, 2005).

In the preamble to the FY 2004 outpatient rule, the Secretary stated that CPT codes do not reflect or properly describe emergency medical services.

> Because these codes were defined to reflect only the activities of physicians, they are inadequate to describe the range and mix of services provided to patients in the clinic and emergency department settings (for example, ongoing nursing care, preparation for diagnostic tests and patient education. . . .
>
> We agree with those commenters who believe that CPT codes for E/M services describe different levels of physician effort, and therefore, fail to accurately describe facility resources used to provide E/M services. (emphasis added)

68 *Fed. Reg.* 63461 & 63463 (November 7, 2003).

See also 67 *Fed. Reg.* 66790 (November 1, 2002) ("It is generally agreed, however, that [these codes] do not describe well the range and mix of services provided by facilities to clinic and emergency patients..."); 67 *Fed. Reg.* 52133 (August 9, 2002) ("the level of service for emergency and clinic visits should be determined by resource consumption that is not otherwise separately payable"); 68 *Fed. Reg.* 18451 (April 7, 2000) ("HCPCS codes appropriately represent different levels of physician effort, they do not adequately describe non-physician resources"); and 63 *Fed. Reg.* 47566 (September 8, 1998) ("CPT codes are more descriptive of physician effort than of facility use...").

We view these statements as an acknowledgement that CPT codes do not form the type of classification system which is demanded by Section 1833(t)(2)(A) of the Act to provide for payment of, among other things, emergency department services. The relegation of services

provided by the Shoreline facility to "clinic" status for payment purposes decreases the accuracy of payment since, as noted above, the charge data upon which the clinic rates are based excludes emergency services. We do not believe that the assignment of emergency services provided by the Shoreline facility to "clinic" status meets the objective of Section 1833(t)(2)(A) that services be reflected in medically coherent (i.e. like) groups for payment purposes. As a matter of law and public policy, CMS should not substitute clinic payment rates, which reflect non-emergency clinic resources, for services that patients customarily receive in an emergency department with emergency department resources. We believe this point is underscored by the fact that, in the absence of the Shoreline facility, patients would still seek emergency department services and receive those services, not clinic services, albeit on a less timely basis.

IV. Services Provided by the Shoreline Facility

Examples of typical emergency cases which are seen at Shoreline are described below and are assigned to the proper CPT code which is available for emergency department services, and which should be available for services provided by the Shoreline facility.

AMA CPT 99285 Clinical Example = Emergency Department visit for a patient with an acute onset of chest pain compatible with symptoms of cardiac ischemia and/or pulmonary embolus.

→ Shoreline Case = Patient arrives by ambulance having suffered a cardiac arrest. ED physician attempts resuscitation. Patient expires and is transported to hospital morgue.

→ Shoreline Case = Patient arrives by ambulance with chest pain. After evaluation, patient is transported by ambulance to the hospital cardiac catheterization lab for primary angioplasty and stenting, bypassing the main campus ED.

AMA CPT 99285 Clinical Example = Emergency department visit for acute febrile illness in an adult, associated with shortness of breath and an altered level of alertness.

→ Shoreline Case = Patient with known seizure disorder arrives by ambulance in status epilepticus. Shoreline ED attending administers seizure medications and febrile convulsions arrest. Patient is discharged.

AMA CPT 99285 Clinical Example = Emergency department visit for a patient with a new onset of a cerebral vascular accident.

→ Shoreline Case = Patient arrives by ambulance having suffered syncope/ collapse. Patient is diagnosed with an aneurysm and transported by ambulance to the hospital for direct admit.

The Shoreline facility maintains the following emergency department medical resources (equipment and supplies) for use in serving its patients. These resources, in the aggregate, are typical of emergency department and not non-emergency clinic resources.

- Telemetry – three (3) hard wire monitors including pressure line system, ST segment analysis, five (5) to seven (7) telemetry packs

- Ventilator and supplies
- Ultrasound
- MRI
- CT scanner
- General radiology
- Uncrossmatched blood – 10 units
- PYXIS units
- Biphasic defibrillator
- Adult and pediatric code carts
- EKG machine
- Slit lamp
- Bair Huggers
- Warming lights – adult and pediatric
- LMA intubation catheters
- Rapid sequence induction drugs
- Peritoneal dialysis supplies – adult and pediatric
- Tenchoff catheter supplies – adult and pediatric
- Thoracotomy trays
- Tracheostomy trays
- Trauma resuscitation trays
- OB Delivery Kits

V. YNHH's Request is Consistent with CMS' Past Practice in Analogous Cases

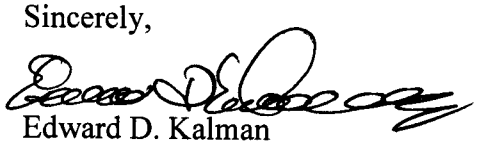
In these circumstances we believe it appropriate for CMS to follow precedent it has established in other situations where it found program instructions to be confusing or inconsistent with best administrative practices. When CMS issued Program Memorandum ("PM") A-99-62 which allowed for charity days to be included within the Medicaid-eligible portion of the disproportionate share calculation ("DSH"), it did so due to instructions it acknowledged were confusing concerning the proper definition of Medicaid-eligible DSH days. Program Memorandum A-99-62 held these hospitals harmless both retrospectively and for a prospective period, which would have allowed for explicit clarifying rulemaking. This Program Memorandum was preceded by the attached letter dated October 15, 1999 from Michael Hash, HCFA Deputy Administrator to the Chairman of the Senate Finance Committee, Senator Roth, which gave notice of a "hold harmless" for hospitals with respect to aspects of the Medicare program's disproportionate share policy because past Medicare guidance "was not sufficiently clear." YNHH respectfully asks the Secretary to follow this precedent with respect to Shoreline and like facilities which exist or are under formation (as verified by the applicable State agency) on the date of adoption of the final FY 2006 OPPS regulation. The payments for services provided by these facilities should be at emergency department rates until the Secretary engages in a formal rulemaking on this issue.

Conclusion

For the foregoing reasons, YNHH submits that any policy adopted by CMS should "grandfather" existing provider-based, part-time emergency departments, including the Shoreline emergency department satellite facility, as entitled to payment at full emergency department rates as of the date they commenced operations.

YNHH thanks the Secretary for his consideration of these comments. Any questions concerning these comments should be directed to the undersigned.

Sincerely,



Edward D. Kalman

Attachment A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

October 15, 1999

The Honorable William V. Roth, Chairman
Senate Finance Committee
219 Direksen Senate Office Building
Washington, DC 20510

Dear Senator Roth:

Knowing of your interest in Medicare's policy for determining certain hospital payment adjustments, I am writing you today to inform you of a new development in this area. The Health Care Financing Administration will hold harmless hospitals that have received certain additional Medicare disproportionate share hospital (DSH) payments because guidance on how to claim these funds was not sufficiently clear.

As you know, the DSH formula provides additional funds to hospitals that serve low income Americans. A review of the practices and policies regarding Medicare DSH determinations leads us to conclude that our guidance on the calculation of Medicare DSH, particularly with regard to the inclusion of general assistance days, was neither sufficiently clear nor well understood. The most recent guidance to hospitals on this matter was provided prior to 1998. Many hospitals, fiscal intermediaries and state Medicaid agencies have differing understandings about the particulars of the DSH calculation. We have been actively gathering facts about practices of entities involved in Medicare DSH determinations, and we now have available the information we need to resolve the confused situation we observe.

We will quickly clarify our Medicare DSH policy in guidance both to our fiscal intermediaries and to hospitals. We will also provide clarification of our policy to state Medicaid agencies to ensure that data they submit for use in making DSH determinations comport with our DSH formula. Medicaid data are critical to the DSH calculation, and the state Medicaid agencies are the primary source of the data in question. The forthcoming guidance will be effective for hospital Medicare cost reporting periods beginning on or after January 1, 2000.

66

ANS
LIFE GETS BETTER

September 8, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed changes to the Hospital Outpatient Prospective Payment System for 2006

Advanced Neuromodulation Systems, Inc. (ANS) is a medical device company, located in Plano, Texas, that manufactures and markets spinal cord stimulation (SCS) systems, also known as neurostimulation systems. These are implantable devices that provide pain relief for chronic pain patients.

ANS appreciates the opportunity to comment on the proposed changes to the Hospital Outpatient Prospective Payment System for 2006, which was published in the Federal Register on July 25, 2005.

Background

SCS is not a new treatment for pain. In 1967 Dr. Norman Sheely of the University of Minnesota developed the concept of electrical stimulation as a pain therapy. Sheely found that pain relief could be achieved by implanting a spinal cord stimulator and an electrical lead with electrodes and using the implanted device to stimulate targeted nerve fibers of the spinal cord. The stimulation of these targeted nerve fibers diminishes or blocks the intensity of the pain message being transmitted to the brain and replaces the areas of intense pain with a more pleasing sensation called paresthesia. The objective of SCS is to reduce or eliminate a patient's level of pain so he or she can return to a more normal lifestyle and resume a roll as a functioning member of his or her family and community.

SCS is FDA-approved for the treatment of chronic intractable pain of the trunk and limbs.

Significant advances in technology, implantation technique, and patient selection criteria over the last 37 years have made SCS a safe and highly effective treatment for chronic intractable pain.

The standard SCS procedure calls for the implantation of an 8-electrode lead or two 4-electrode leads and an implantable pulse generator (IPG) system utilizing a non-rechargeable battery, which provides the power needed for electrical stimulation. Once a non-rechargeable IPG's power is depleted, the patient requires a surgical procedure to replace it. The non-rechargeable IPG systems offered in the marketplace today have a limited life expectancy, which depends on the amount of power required to provide adequate pain relief. Under average power usage, the life expectancy of a non-rechargeable IPG is approximately three years. However, for patients who have a higher-than-average power need in order to achieve pain relief, the IPG could deplete in less time than the previously stated three years. In fact, there are documented cases where these power supplies required replacement surgery in less than one year. SCS technology has evolved, and as a result, rechargeable SCS systems have been introduced to the market place. These new systems are

ADVANCED NEUROMODULATION SYSTEMS
6901 Preston Road ▪ Plano, TX 75024
972-309-8000 ▪ www.ans-medical.com

rechargeable IPG systems, which power up to 16 electrodes (two 8-electrode leads). Rechargeable IPGs allow patients with high power needs to achieve adequate pain relief without the concern for premature power depletion. Additionally, the implantation of up to 16 electrodes provides broader stimulation coverage and offers several clinical benefits, including the reduction of additional surgeries required to rectify a common complication, lead migration. Lead migration occurs when a lead moves off the targeted nerve fibers and is usually caused by excessive patient movement. When this occurs, targeted stimulation and pain relief may be lost, requiring an additional surgical procedure to reposition the lead. With 16 electrodes, the physician has the flexibility to electronically retarget the nerve fibers that provide pain relief through non-invasive programming, thus eliminating the need for this revision surgery.

In July of 1999, ANS introduced the 16-electrode Renew® radio-frequency (RF) system with therapy capabilities comparable to those of the new 16-electrode rechargeable IPG systems. And while these systems provide similar therapy, an RF system demands a much greater level of patient ability and compliance than does an IPG system. In addition to the lead component, an RF system consists of an implantable receiver, an external transmitter, and an external antenna, which is connected to the transmitter and which must stay in constant contact with the receiver. With an RF system, patients have to affix the external antenna, generally with an adhesive pad, to their skin directly over the implanted receiver in order to receive pain-relieving stimulation from the system. They must wear it continuously, even while sleeping, or forego pain relief. As a result of the external antenna, many patients develop skin irritations and skin erosion, leading to problems with therapy compliance and the need for additional medical care. Moreover, patients cannot wear the antenna when showering, bathing, or swimming. This means that chronic pain patients are unable to receive pain relief during these activities of daily living.

Until the recent introduction of 16-electrode rechargeable IPG systems, physicians were reluctant to prescribe 16-electrode systems because of the patient compliance issues with RF systems already stated. In turn, the majority of patients with complex chronic pain—patients who needed the higher power output and additional electrodes of the RF systems for adequate pain relief—received conventional IPGs. Due to these patients' high power requirements and resulting battery depletion, their conventional IPG systems had to be frequently replaced through additional surgery, as mentioned earlier.

The advent of totally implantable, 16-electrode rechargeable SCS systems represents an advance in technology that will significantly improve the treatment and quality of life of patients who suffer from complex chronic pain. These rechargeable systems provide the broad coverage and continuous high power output needed by this subset of patients and eliminate the complications that arise from being tethered to an external antenna. With them, physicians can meet these patients' long-term therapy needs, and patients can receive uninterrupted pain relief, without the need for frequent battery replacement surgeries. This new rechargeable IPG technology will address a complex clinical need and will result in a significant cost savings to the healthcare system over time.

ANS introduced an 8-electrode rechargeable IPG system in February of 2005 and was approved by the FDA to market a 16-electrode rechargeable IPG system in March of 2005.

Advanced Bionics and Medtronic are the other two companies that manufacture and market SCS devices. Advanced Bionics introduced a 16-electrode rechargeable IPG system in April 2004, while Medtronic's 16-electrode rechargeable IPG system received FDA approval in the spring of 2005. These new rechargeable IPGs have been approved for having battery lives ranging from 5 to 9 years.

Transitional Pass-Through Payments for Devices

During the comment period for the proposed changes to the Hospital Inpatient Prospective Payment System for 2006, ANS, Medtronic, and Advanced Bionics independently submitted information to CMS in an effort to obtain **new technology add-on payments** for rechargeable IPGs and their associated patient recharging systems. In the final IPPS ruling, published on August 12, 2005, CMS granted these additional payments. ANS applauds CMS for this approval, which will allow chronic pain patients access to these new devices if the procedures are performed in the hospital inpatient setting.

Furthermore, ANS agrees with CMS' proposal "to create an additional category for devices that meet all of the criteria required to establish a new category for pass-through payment in instances where … an existing or previously existing category descriptor does not appropriately describe the new type of device." This proposal, if approved, would allow CMS to review and, if warranted, approve device codes and pass-through payments for **rechargeable** IPGs and their patient recharging systems.

The three companies also submitted to CMS information in support of obtaining transitional **pass-through payments** for these devices for procedures performed in the hospital outpatient setting. We are currently awaiting CMS' decision and are hopeful it will mirror the outcome from the inpatient ruling.

Concerns regarding the proposed changes to the Hospital Outpatient Prospective Payment System for 2006

I. Reconfiguration of APC 0040 (Level I, Implantation of neurostimulator electrodes) and APC 0225 (Level II, Implantation of neurostimulator electrodes)

ANS has concerns about the proposed reconfiguration of APC 0040 and APC 0225, specifically the movement of CPT 63655 and CPT 64580 to APC 0040 from APC 0225. The reconfigurations would result in these two APCs being neither clinically cohesive nor cost-cohesive and, in some instances, would violate the "two-times" rule. These reconfigurations would also result in the above CPT codes experiencing a 72.6% payment decrease.

Because of these concerns, ANS, along with Medtronic and Advanced Bionics, co-sponsored a petition to reformulate the CPT codes from APC 0040 and APC 0225 into three APC codes. This petition, which was presented to the APC Panel on August 18, included two presentations that highlighted the clinical and economic issues surrounding these codes. Dr. Richard North, a neurosurgeon with Johns Hopkins University Hospital in Baltimore, Maryland, presented the clinical differences of the procedures associated with these APCs (see Attachment A). Ms. Bonnie Handke, Senior Reimbursement Manager, Health Policy and Payment at Medtronic, presented the economics of the APCs (see Attachment B).

The APC Panel endorsed this petition and is recommending this new reconfiguration to CMS. If reconfigured thus, the three APCs would be both clinically cohesive and cost-cohesive (see Recommendations pages in Attachment B). ANS is in full agreement with the APC Panel's recommendation.

II. Significant payment rate reduction for APC 0222 (Implantation of neurological device)

APC 0222 includes the implantation of **non-rechargeable** IPGs and their patient programmers, **rechargeable** IPGs and their patient programmers and recharging systems, and RF system receivers and transmitters.

In the 2006 proposed ruling, the payment rate for APC 0222 was reduced from $12,372.71 for 2005 to $10,628.22, equaling a 14.1% decline. This proposed payment rate will not cover the costs of performing these procedures and, if left unchanged, will deny patients access to these devices. APC 0222 is a "device-dependant APC," where the payment rate is intended to cover both the device-related costs as well as the procedure-related costs. In 2005, the procedure-related portion of the $12,372.71 payment rate was $1,708.67. If the procedure-related portion of the payment rate were estimated to be the same for 2006 as it was for 2005, only $8,919.55 ($10,628.22 - $1,708.67) would remain to cover the device-related costs for the procedure.

As mentioned above, the ANS family of products includes rechargeable and non-rechargeable IPGs and RF systems. The hospital acquisition costs for these ANS devices range from $10,190.00 to $17,190.00. The average system cost is $14,823.81 based on actual usage mix. This amount breaks down to $13,701.36 for non-rechargeable IPG systems (to include the IPG and patient programmer), $16,759.56 for re-chargeable IPG systems (to include the IPG, patient programmer, and recharging system) and $15,573.43 for RF systems (to include the receiver and transmitter). Our estimated share of the entire SCS market is 24%.

Moreover, because device codes (C-codes) were not mandatory for reimbursement filing in 2004, the hospital data used to generate the 2006 payment rates appears to be inaccurate and subsequently understates the actual costs of these procedures. In order to allow patients access to these vital procedures, and until more reliable hospital cost data can be collected, ANS recommends implementing one of two scenarios:

1. Hold the 2005 reimbursement rates intact and add the 3.2% market basket increase update, or

2. Use external data that accurately reflects the true hospital acquisition cost for these devices.

If you have any questions or require any additional information about ANS products (e.g., product mix, market share, or cost), please do not hesitate to call me at 800-727-7846, Extension 8034. ANS representatives are also available to meet with you at your convenience.

Thank you for your review of this information and your consideration in this matter.

Sincerely,

Mark P. Barulich
Director, Sales Support

MB/jfy

Attachment A

Neurostimulator Electrode Implantation Issue

Advisory Panel on Ambulatory Payment Classification (APC) Groups

Second Biannual Meeting
August 18, 2005

Richard North, MD
Neurosurgeon
Assistant Professor
Johns Hopkins University Hospital

Attachment A

Neurostimulation Applications

- Control chronic pain
  - Spinal cord stimulation / peripheral stimulation
- Control movement disorders
  - Intracranial stimulation
- Control seizures
  - Intracranial stimulation
- Control bladder function
  - Peripheral stimulation

Attachment A

Spinal Cord Stimulation (SCS)

- An advanced treatment for certain types of chronic pain
- Low level electrical impulses stimulate targeted nerves along the spinal cord
- The stimulation interferes with the transmission of pain signals to the brain
- Pain is replaced with a more pleasing sensation called "paresthesia"

Attachment A

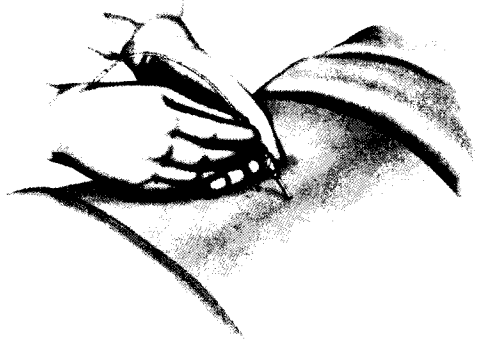
Typical Neurostimulation System

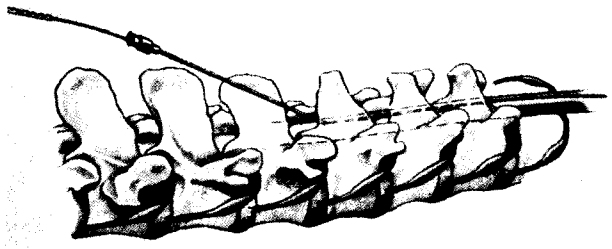
- Electrodes (implanted)
  - Multiple contacts attached to catheter body (lead) containing insulated wires leading to connector
  - Implanted in a targeted area above the spinal cord (epidural space)
  - Two types:
    - Percutaneous (same diameter as lead and can be introduced by needle)
    - Laminectomy (wider than lead with insulated paddle/plate contacts and requires laminectomy)
- Pulse generator (implanted)
  - Power source that provides electrical impulses to contacts on implanted electrode
  - Typically implanted in the lower trunk of the body
- Patient Programmer (external)
  - Allows patient to adjust stimulation levels

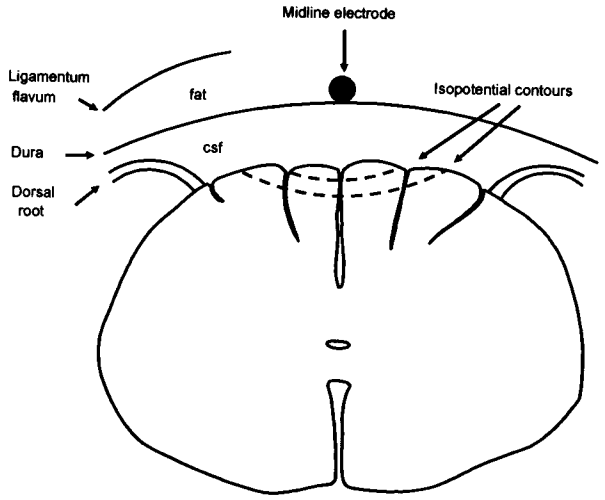
Attachment A

Percutaneous Implantation

- Typically performed by anesthesiologist
- Electrode is same diameter as thin, guide-wire controlled, catheter-like lead and has circumferential metal contacts
- Inserted percutaneously, through a specially designed spinal needle into epidural space
- Less invasive procedure = lower risk to patient
- Less effort by physician (RVU = 10.44)
- Less expensive than laminectomy electrode



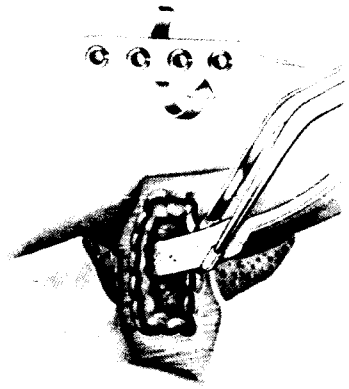


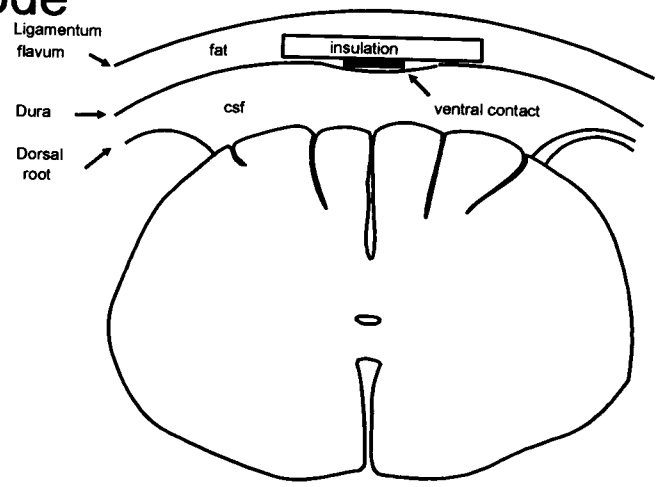


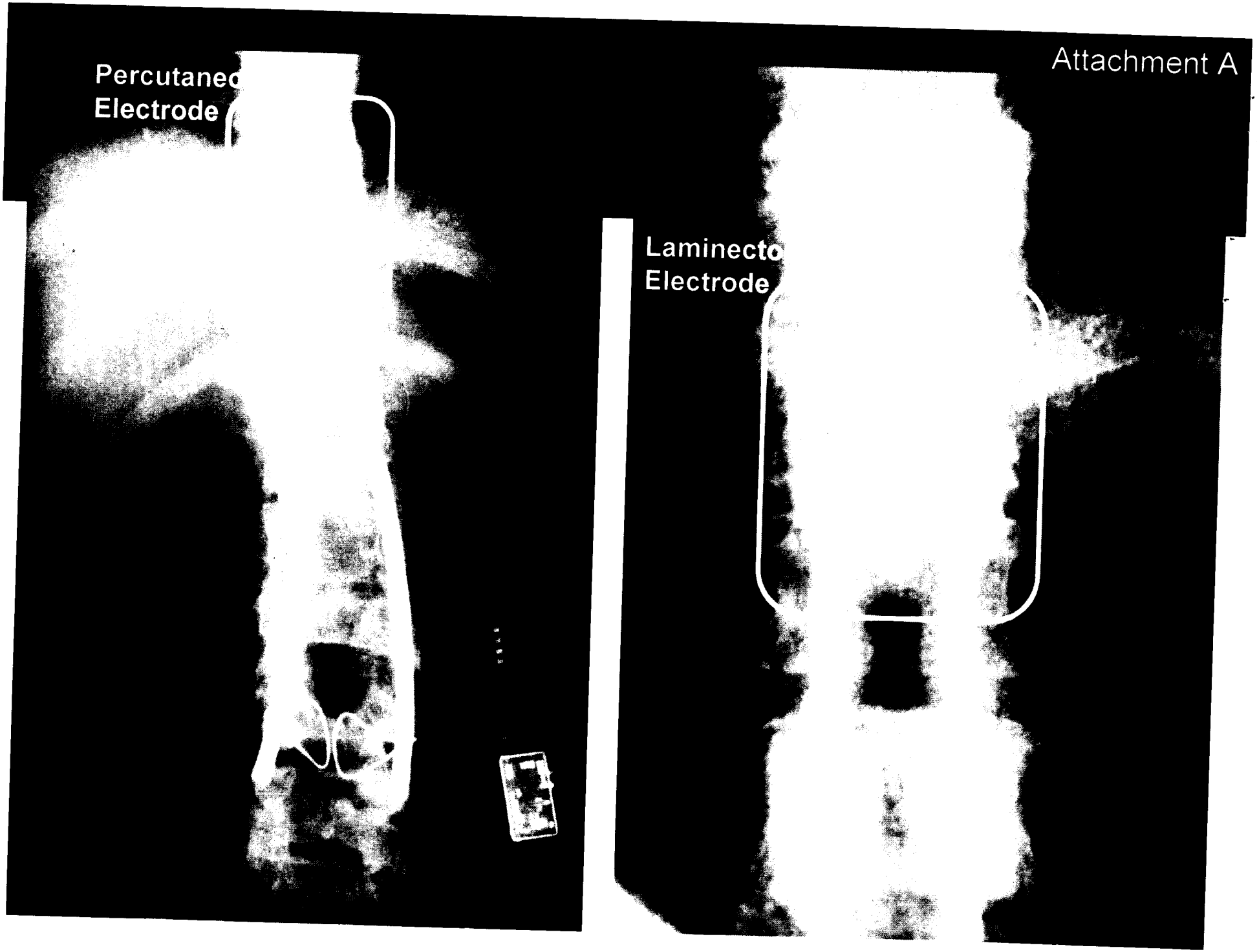
Attachment A

Laminectomy for Implantation

- Typically performed by neurosurgeon or orthopaedic surgeon
- Electrode is wider than the lead and paddle-shaped with flat, plate-type metal contacts
- Spinal ligaments and lamina removed to allow for passage of electrode into epidural space
- Invasive procedure = higher risk to patient
- Significant effort by physician (RVU = 19.49)
- More expensive than percutaneous electrode






Percutaneo
Electrode
Laminecto
Electrode
Attachment A

Attachment A

Laminectomy electrode benefits

- Patient access
  - Percutaneous placement not always feasible
- Performance
  - Class 1 evidence (RCT) shows
    - Increased paresthesia coverage
      - VAS ratings, pain drawings
      - scaled amplitude to cover low back
    - Reduced power requirements

Attachment A

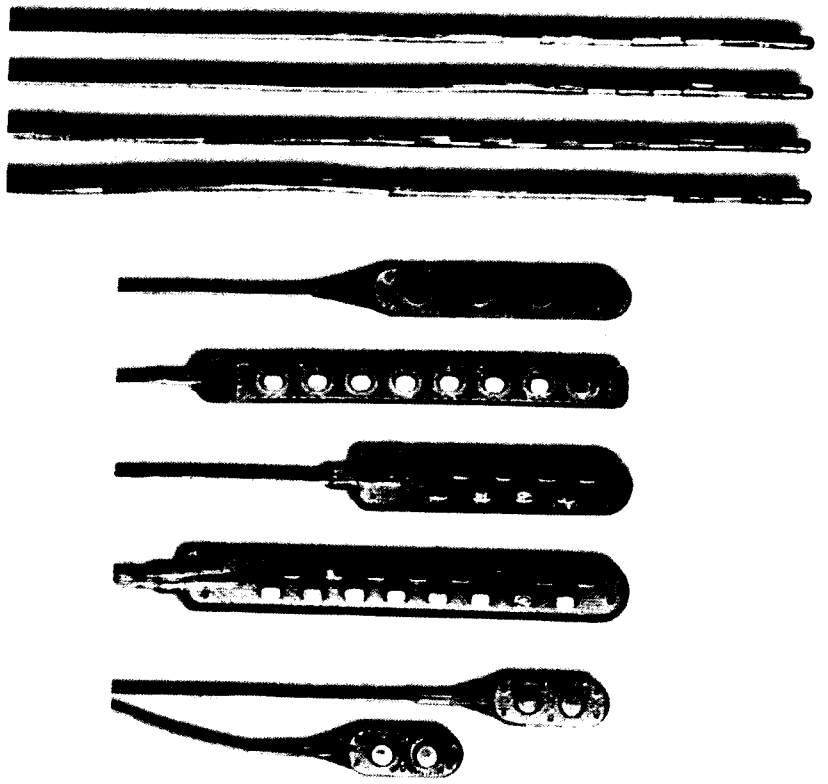
Issue

- Historically, percutaneous implantation and laminectomy implantation have been in different APCs
- 2006 OPPS NPRM proposal to reconfigure APC 0225 and APC 0040 is clinically incongruent

Attachment A

Recommendation

- Further reconfigure APCs to recognize clinical differences between percutaneous and laminectomy electrode implantation procedures



Attachment B

Meeting of the Advisory Panel on Ambulatory Payment Classification (APC) Groups

Implantation of Neurostimulator Electrodes

APCs 0040 and 0225

August 17-19, 2005

Bonnie Handke, RN, Medtronic, Inc.

On Behalf of Advanced Bionics, Advanced Neuromodulation Systems and Medtronic, Inc.

Attachment B

Financial Disclosure

- I am an employee and stockholder of Medtronic, Inc.
- Medtronic is one of three companies that creates the products that are the subject of this presentation.

Attachment B

Description of Issue

- 2006 NPRM reconfigurations of APC 0040 and APC 0225
  - Specifically – movement of CPTs 63655 and 64580 to APC 0040 from APC 0225
- Impact
  - APCs not clinically cohesive
  - APCs not cost cohesive
    - Violation of two times rule
  - Results in 72.7% payment decrease for these CPTs

Attachment B

Clinical Description of the Service

- Percutaneous Lead Implantation
  - Typically performed by anesthesiologist
  - Electrode is same diameter as thin, guide-wire controlled, catheter-like lead and has circumferential metal contacts
  - Inserted percutaneously, through a specially designed spinal needle into epidural space
  - Less invasive procedure = lower risk to patient
  - Less effort by physician (RVU = 6.74)
  - Less expensive than laminectomy electrode

Attachment B

Clinical Description of the Service

- Lead Implantation with Laminectomy
  - Typically performed by neurosurgeon or orthopaedic surgeon
  - Electrode is wider than the lead and paddle-shaped with flat, plate-type metal contacts
  - Spinal ligaments and lamina removed to allow for passage of electrode into epidural space
  - Invasive procedure = higher risk to patient
  - Significant effort by physician (RVU = 10.29)
  - More expensive than percutaneous electrode

Attachment B

NPRM 2006 APC 0040 CPT Assignment

- APC 0040 – Proposed Payment $3,268 (Median cost $3,338)
  - 63650 - Implant electrode-perc-spinal
    - **Accounts for 62.7% of claims used in rate setting**
    - **Median cost $2,866**
  - 64555 - Implant electrode-perc-peripheral
  - 64560 - Implant electrode-perc-autonomic
  - 64561 - Implant electrode-perc-sacral
  - 64565 - Implant electrode-perc-neuromuscular
  - 64575 - Implant electrode-incision-peripheral
    - **Median cost $5,815**
  - 64581 - Implant electrode-incision-sacral
    - **Median cost $5,501**
  - 63655 - Implant electrode-lami-spinal
    - **Median cost $5,746**
  - 64580 - Implant electrode-incision-neuromuscular
    - **Median cost $3,362.**

Attachment B

NPRM 2006 APC 0225 CPT Assignment

- APC 0225 - Proposed Payment - $13,865 (Median Cost $14,162)
  - 64553 - Implant electrode-perc-cranial
    - Median cost $12,064
  - 64573 - Implant electrode-incision-cranial
    - Median cost $14,510
  - 64577 - Implant electrode-incision-autonomic
    - Median cost $11,312

Attachment B

Recommendations and Rationale for Change

- Recommendations
  - Reconfigure proposed APCs 0040 and 0225 to reflect percutaneous and cranial lead procedures, respectively
  - Create a third APC to reflect lead procedures that require incisions or laminectomies
- Rationale
  - Eliminate two times violation
  - APCs will be clinically and cost cohesive

Attachment B

Recommendations: Alternative 2006 APC Reconfigurations

APC	CPT	Description	Total Median Cost (2004)	"Single" Frequency	Total Frequency	New Median Cost
0040 **LEVEL I** 2006 NPRM Median Cost $3,338	63650	Impl. Electrode – Perc – Spinal	$2,866.51	1596	7284	$2,694
	64555	Impl. Electrode – Perc – Peripheral	$2,647.95	122	258	
	64560	Impl. Electrode – Perc – Autonomic	$3,837.47	2	5	
	64561	Impl. Electrode – Perc – Sacral	$3,822.65	460	1714	
	64565[1]	Impl. Electrode – Perc – Neuromuscular	$16,032.74	5	8	
0225 **LEVEL III** 2006 NPRM Median Cost $14,162	64553	Impl. Electrode – Perc – Cranial	$12,064.27	31	126	$13,808
	64573	Impl. Electrode – Incision – Cranial	$14.510.28	153	813	
New APC **LEVEL II**	64577[2]	Impl. Electrode – Incision – Autonomic	$11,312.99	1	2	$5,432
	64580	Impl. Electrode – Incision – Neuromuscular	$3,362.63	3	7	
	64575	Impl. Electrode – Incision – Peripheral	$5,815.60	26	144	
	64581	Impl. Electrode – Incision – Sacral	$5,501.20	332	1442	
	63655	Impl. Electrode – Lami – Spinal	$5,746.58	69	553	

[1]CPT 64565 – outlier – last year median cost $59
[2]CPT 64577 – outlier – only one claim used to set rate

Consequences of No Change

- Creates inappropriate financial incentives without regard to medically appropriate care
- Barriers to access if payment rates are inadequate
- APCs are not clinically and cost cohesive
- Laminectomy/Incision for implantation of electrodes subject to inappropriate 72.7% payment decrease

Attachment B

Recommendations: Summary

2005 APC Groups

CPT	CPT Description	APC
63650	**Percutaneous** implantation of neurostimulator electrode array, EPIDURAL	0040
64555	**Percutaneous** implantation of neurostimulator electrode array, PERIPHERAL NERVE	0040
64560	**Percutaneous** implantation of neurostimulator electrode array, AUTONOMIC NERVE	0040
64561	**Percutaneous** implantation of neurostimulator electrode array, SACRAL NERVE	0040
64565	**Percutaneous** implantation of neurostimulator electrode array, NEUROMUSCULAR	0040
64575	Incision for implantation of neurostimulator electrodes, PERIPHERAL NERVE	0040
64581	Incision for implantation of neurostimulator electrodes, SACRAL NERVE	0040

Median Cost = $2,885

63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle(s), EPIDURAL	0225
64553	**Percutaneous** implantation of neurostimulator electrodes; CRANIAL NERVE	0225
64573	Incision for implantation of neurostimulator electrodes; CRANIAL NERVE	0225
64577	Incision for implantation of neurostimulator electrodes; AUTONOMIC NERVE	0225
64580	Incision for implantation of neurostimulator electrodes; NEUROMUSCULAR	0225

Median Cost = $12,328

NPRM 2006 APC Groups

CPT	CPT Description	APC
63650	**Percutaneous** implantation of neurostimulator electrode array, EPIDURAL	0040
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle(s), EPIDURAL	0040
64555	**Percutaneous** implantation of neurostimulator electrode array, PERIPHERAL NERVE	0040
64560	**Percutaneous** implantation of neurostimulator electrode array, AUTONOMIC NERVE	0040
64561	**Percutaneous** implantation of neurostimulator electrode array, SACRAL NERVE	0040
64565	**Percutaneous** implantation of neurostimulator electrode array, NEUROMUSCULAR	0040
64575	Incision for implantation of neurostimulator electrodes, PERIPHERAL NERVE	0040
64580	Incision for implantation of neurostimulator electrodes; NEUROMUSCULAR	0040
64581	Incision for implantation of neurostimulator electrodes, SACRAL NERVE	0040

Median Cost = $3,338

64553	**Percutaneous** implantation of neurostimulator electrodes; CRANIAL NERVE	0225
64573	Incision for implantation of neurostimulator electrodes; CRANIAL NERVE	0225
64577	Incision for implantation of neurostimulator electrodes; AUTONOMIC NERVE	0225

Median Cost = $14,162

Alternative 2006 APC Groups

CPT	CPT Description	APC
63650	**Percutaneous** implantation of neurostimulator electrode array, EPIDURAL	0040
64555	**Percutaneous** implantation of neurostimulator electrode array, PERIPHERAL NERVE	0040
64560	**Percutaneous** implantation of neurostimulator electrode array, AUTONOMIC NERVE	0040
64561	**Percutaneous** implantation of neurostimulator electrode array, SACRAL NERVE	0040
64565	**Percutaneous** implantation of neurostimulator electrode array, NEUROMUSCULAR	0040

Median Cost = $2,694

64553	**Percutaneous** implantation of neurostimulator electrodes; CRANIAL NERVE	0225
64573	Incision for implantation of neurostimulator electrodes; CRANIAL NERVE	0225

Median Cost = $13,808

63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle(s), EPIDURAL	new
64575	Incision for implantation of neurostimulator electrodes, PERIPHERAL NERVE	new
64577	Incision for implantation of neurostimulator electrodes; AUTONOMIC NERVE	new
64580	Incision for implantation of neurostimulator electrodes; NEUROMUSCULAR	new
64581	Incision for implantation of neurostimulator electrodes, SACRAL NERVE	new

Median Cost = $5,432

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David Fried '67
(651) 636-3878
(651) 238 2534

August 17, 2005

Mr. James S. Hart
Deputy Director, Division of Acute Care
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
PO Box 8016
Baltimore, MD 21244-8018

Dear Jim:

RE: Riverain Medical's Recommendation for Chest X-ray CAD Add On

Thank you for the opportunity to propose a mechanism that allows reimbursement for use of Riverain Medical's RapidScreen® chest radiography (X-ray) computer-aided detection (CAD). My recommendation is for New Technology Ambulatory Payment Classification (APC) Group 1498 beginning January 1, 2006.

Clinical Benefit of RapidScreen

In the clinical study leading to the approval of RapidScreen (PMA P000049), the detection rate of cancer nodules < 15mm increased by more than 20%.

CPT Code for Chest Radiograph CAD Add On

The AMA editorial board recently assigned chest X-ray CAD Category III CPT Code*, which became effective July 1, 2005:

"0152T Computer-aided-detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; chest radiograph(s) (List separately in addition to code for primary procedure)"

(Use 0152T in conjunction with 71010, 71020, 71021, 71022, and 71030).

- 71010 Radiologic examination, chest; single view, frontal
- 71020 Radiologic examination, chest, two views, frontal and lateral
- 71021 Radiologic examination, chest, two views, frontal and lateral; with apical lordotic procedure
- 71022 Radiologic examination, chest, two views, frontal and lateral; with oblique projections
- 71030 Radiologic examination, chest, complete, minimum of four views

*Category III CPT Code allows private third party payer coverage for the use of RapidScreen.

Estimated RapidScreen Chest Radiography (X-Ray) CAD Use

Riverain Medical expects CAD to be used in people at high risk for lung cancer, such as smokers, former smokers, non-smokers living with smokers, and people subjected to occupational and environmental carcinogens. Riverain Medical estimates that about 60% of Medicare patients are high-risk.

Riverain Medical anticipates about 40% of the total use will be in Medicare patients; the other 60% will be used in non-Medicare patients. Riverain Medical projects that RapidScreen will be used in

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approximately 850,000, 2 million, and 3.5 million chest X-rays of Medicare patients in 2006, 2007, and 2008, respectively.

Riverain Medical estimates 720, 1,080, and 1,200 RapidScreen units will be installed in 2006, 2007, and 2008, respectively, at an average purchase price of $162,000. Based on our market information, there are approximately 80,000,000 total chest x-rays procedures per year of which 18 million are from the Medicare population. Approximately 35% of total chest x-rays are captured by non-portable devices.

RapidScreen will have a life cycle of approximately three years for either the analog version or the digital version. The cost for RapidScreen is $162,000; $150,000 for the Analog version and $165,000 for the digital version. Riverain Medical expects 80% of the installed units will be digital and 20% will be analog, which reflects an average acquisition price of $162,000.

Summary Table & Analysis of RapidScreen Utilization

Year	Annual Installation Units	Average acquisition price/unit	Total Medicare utilization per year (# X-rays/yr)	Total Non-Medicare utilization per yr	APC group	Medicare payment rate (technical fee only)	Non-Medicare payment rate (technical fee only)
2006	720	$162,000	842,000	1,260,000	1498	$25.00	$30.50
2007	1,080	$162,000	2,106,000	3,159,000	1498	$25.00	$30.50
2008	1,200	$162,000	3,510,000	5,265,000	1498	$25.00	$30.50

Medicare assumptions

- 18,000,000 chest X-rays per year
- 65% X-rays are usable (i.e., non-portable)
- 60% of patients are high-risk for cancer

Non-Medicare assumptions

- 60,000,000 chest X-rays per year
- 65% X-rays are usable (i.e., non-portable)
- 27% of patients are high-risk for cancer

Financial assumptions

- $162,000 Average acquisition price per unit
- Three (3) year depreciation of analog and digital equipment
- Unit mix is estimated at 80% digital; 20% analog
- Each unit consists of 90% software / 10% hardware
- The average estimated private third party reimbursement is 22% more than Medicare.

75.26

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Professional Fee

Per your request, my recommendations are for the technical fee portion of reimbursement. As is customary, my assumption is that the professional fee will be a separate submission by the physician.

Other Relevant Information

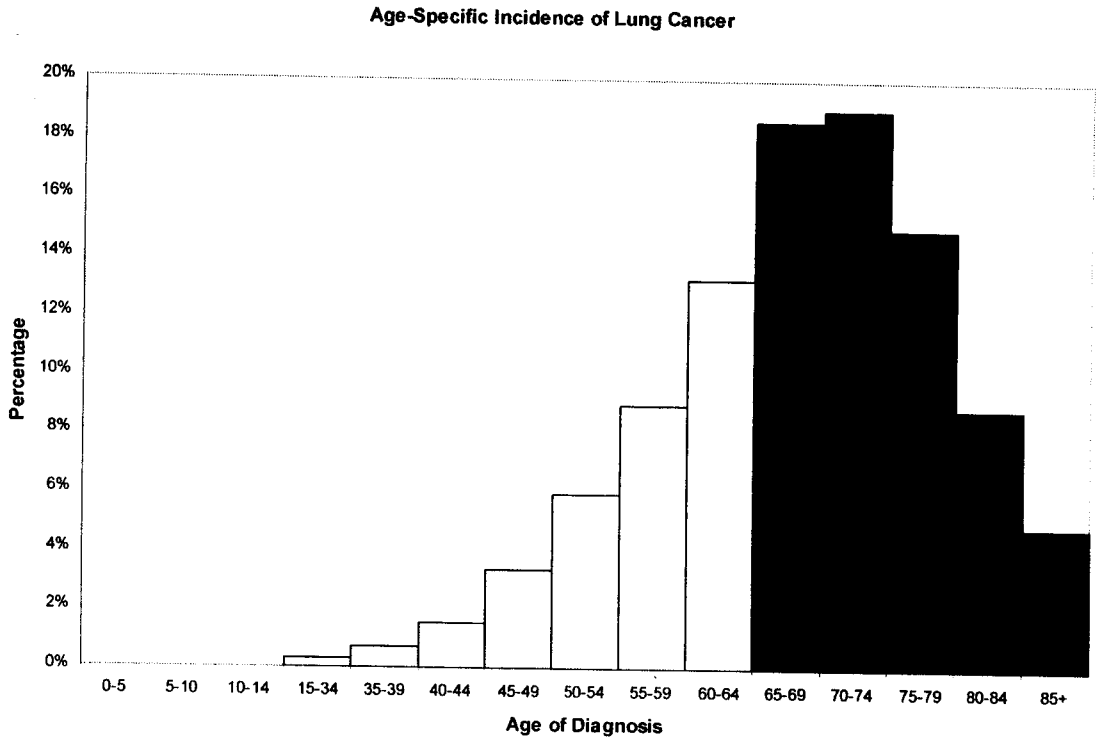
I have provided other important information below, for your convenience:

- 2005 Medicare payment rates for Mammography, Mammography CAD add-on, Chest X-ray and Chest X-ray CT,
- Age specific incidence of lung cancer, and
- Five-year survival rate by stage of cancer at its detection.

Medicare Payment Rates 2005

	CPT-Global		CPT- Technical Component		CPT – Professional Component		Ambulatory Payment Classification		Total Payment
Procedure	Code	Rate	Code	Rate	Code	Rate	Code	Rate	Amount
Mammogram	76091	$97.51	76091-TC	$52.03	76091-26	$45.48	None	N/A	$97.51
	76092	$85.75	76092-TC	$49.00	76092-26	$36.74			$85.75
Mammogram CAD add-on	76082	$19.26	76082-TC	$15.86	76082-26	$3.39	None	N/A	$19.26
	76083	$19.26	76083-TC	$15.86	76083-26	$3.39			$19.26
Chest X-ray	71020	$36.24	71020-TC	$24.87	71020-26	$11.37	0260	$44.38	$55.75
Chest CT	71250	$295.91	71250-TC	$235.28	71250-26	$60.62	0332	$195.04	$255.66

Approximately 172,000 new cases of lung cancer and 160,000 deaths due to lung cancer are expected in 2005[1]. It is important to cover the Medicare Population because approximately two-thirds of lung cancer patients are diagnosed at age 65 or later (see Figure[2] below.)



It is extremely important to detect lung cancer early. A patient is classified by stage of lung cancer at diagnosis. The five-year survival rate decreases as the stage at detection increases:

Stage at diagnosis	Five-year survival rate[3] (%)
I	49[4]
II	26
III	8
IV	2

A recent publication in this year's June 23 edition of the New England Journal of Medicine indicates a five-year survival of 69% in a group of patients randomized to adjuvant chemotherapy after successful lung resection[5].

[1] Source: American Cancer Society 2005 Facts and Figures
[2] Source: Environmental Protection Agency
[3] Source: American Cancer Society Web site, April 2005
[4] Source: American Cancer Society 2005 Facts and Figures
[5] Winton T, Livingston R, Johnson D, et. al. Vinorelbine plus Cisplatin vs. Observation in resected Non-Small Cell Lung Cancer. N Engl J Med 2005;352:2589-97

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I trust that you will find this information helpful. Please call me if you require any additional information at either 800.990.3387 or my mobile phone at 330.284.3264.

Once again, we would like to extend our sincerest thanks for your continuing support to include chest X-ray CAD (computer aided detection) add on for 2006 Medicare reimbursement.

Sincerely,

RIVERAIN MEDICAL

Sam D. Finkelstein

Sam D. Finkelstein
President

SF: sdf

cc: Mr. Don Thompson, Director Ambulatory Services, CMS
Mr. Richard F. Glennon, Chairman, Riverain Medical
Dr. David S. Fryd, VP of Clinical Research, Riverain Medical
Mr. Michael D. Bromberg, Capital Health Care Group
Mr. Sean Coughlin, Capital Health Care Group

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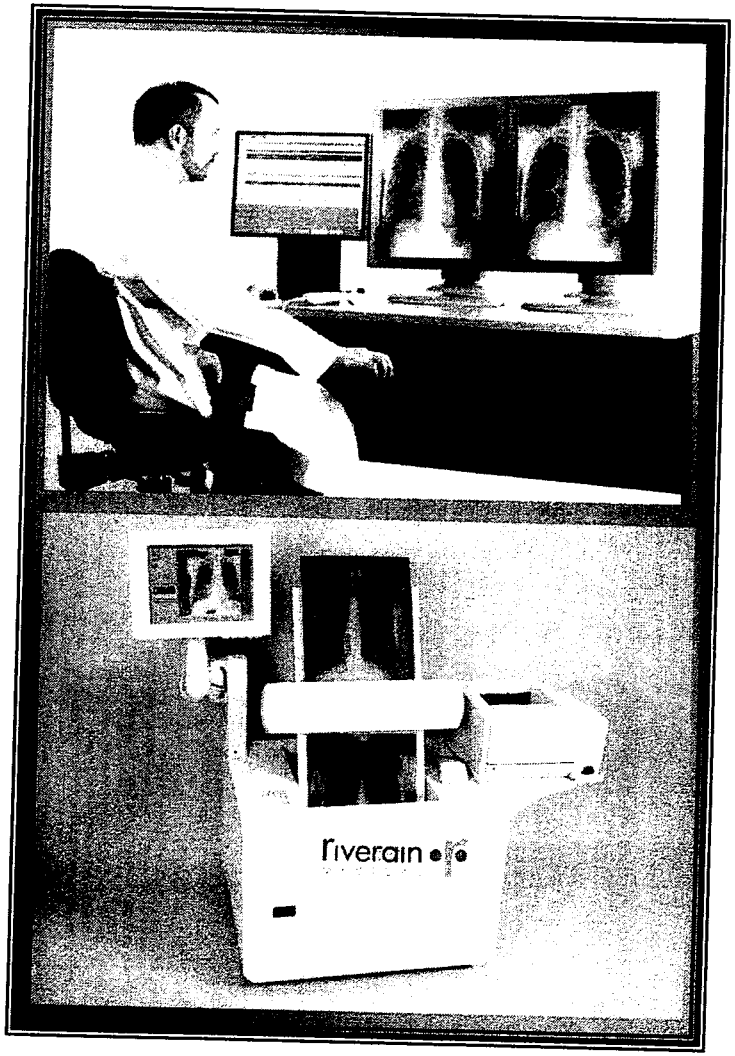


Early Lung Cancer Detection With X-Ray CAD

(Computer-Aided Detection)

Riverain Medical: represented by

Riverain Medical Group

- Richard F. Glennon, Chairman
- Sam D. Finkelstein, President and CEO
- David Fryd, Ph.D. & VP Clinical Affairs
- Matthew Freedman, M.D. MBA

Capitol Health Group

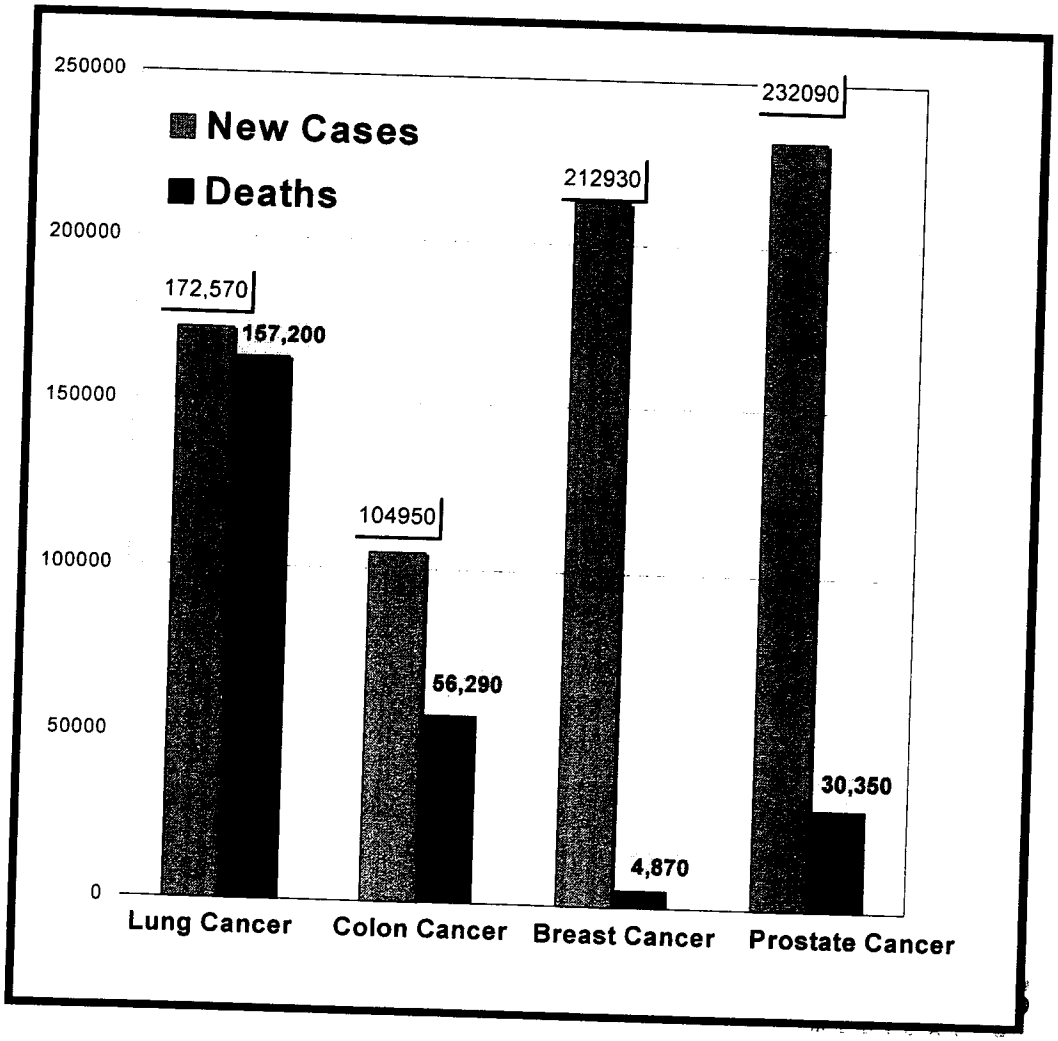
- Shawn Coughlin, Consultant

Lung Cancer is the Leading Cancer Killer

- Lung Cancer is the number one cancer killer, taking more lives annually than breast, colon, and prostate cancers combined.

- More women die of lung cancer every year than of breast cancer.

Source: American Cancer Society Cancer Facts and Figures 2005



Effect of Lung Cancer by Gender

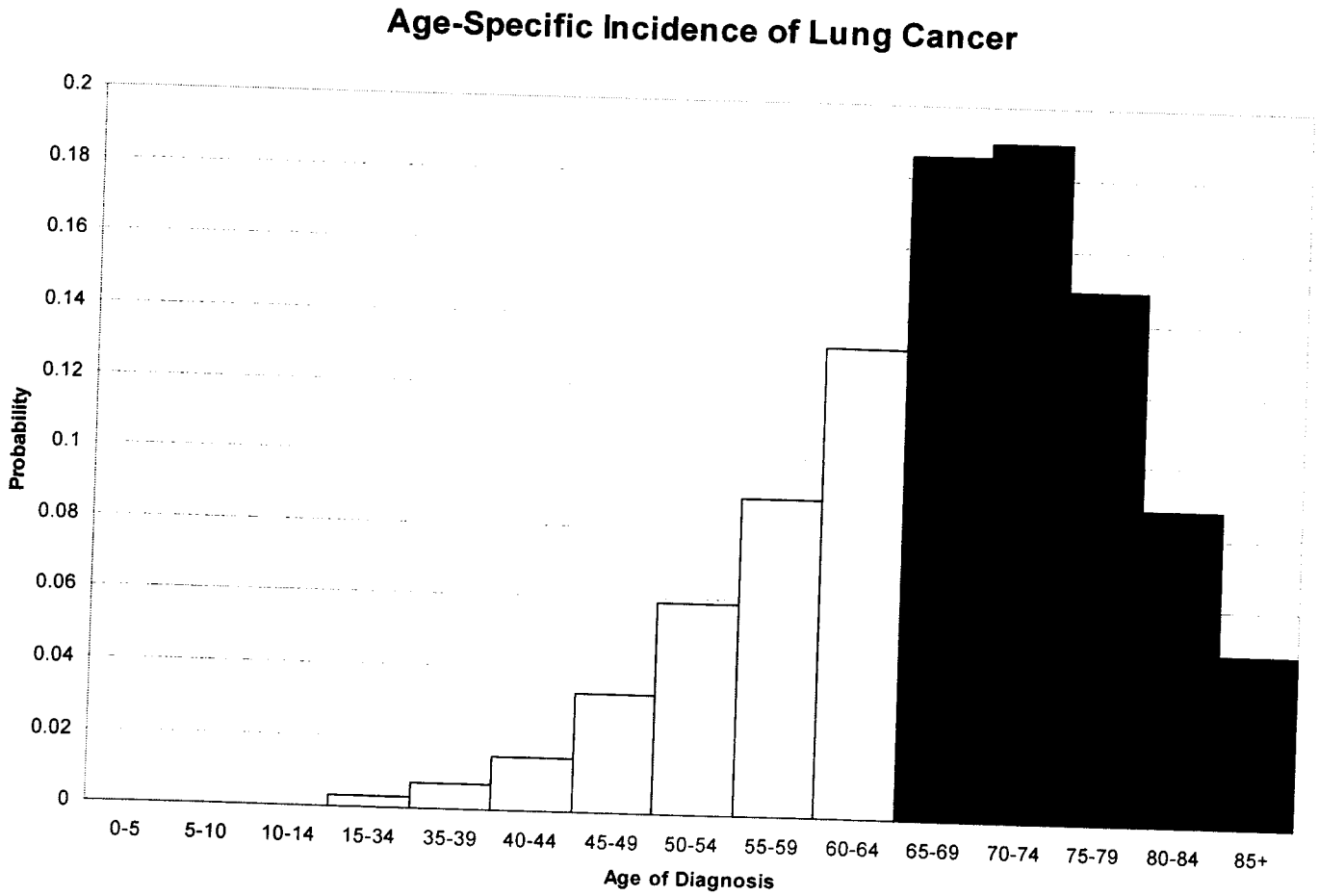
	Males	Females	TOTAL
New Cases	93,010	79,560	172,570
Deaths*	90,490	73,020	163,510

*2005 ACS estimates

Effects of Lung Cancer By Race

ACS – 2005 Estimates – Facts & Figures	White	African American	Hispanic / Latino
Incidence / 100,000	129.2	171.7	69.1
Mortality / 100,000	118.2	144.0	54.5

2/3 lung cancer within Medicare Population



Source: Environmental Protection Agency

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Potential Opportunity of CAD

- X-Ray Computer-Aided-Detection (CAD) can improve five-year survival from the current 15% to 49%* by detecting cancer when it is localized
  - *Source ACS: Facts and Figures 2005
  - Preferably Stage 1A (9-30 mm)

	% diagnosed	5-year survival rate	number of patients in Stage	number reaching 5 year survival
Stage I	16%	49%	27,611	13,529
Stage II-IV	84%	9%	144,959	12,356
All Stages diagnosed 2005 (estimate)	100%	15%	172,570	25,886

Saving Lives Through Early Detection

- X-Ray CAD is proven to increase case finding by 21% at the 9 – 14 mm stage.
  - FDA approved PMA July 2001 for early detection of lung cancer on the basis of this study
  - FDA convened expert panel recommended approval.
- X-Ray CAD may increase case finding of Stage I by 40% in practice.
  - Chest x-ray screening identifies approximately 50% of cancers in Stage I*.
  - * Dominioni L. Imperatori A. Rovera F. Ochetti A. Torrigiotti G. Paolucci M. Stage I nonsmall cell lung carcinoma: analysis of survival and implications for screening. [Review] [62 refs] Cancer. 89(11 Suppl):2334-44, 2000 Dec 1.

Saving Lives Through Early Detection

- X-Ray CAD is a low-cost technology for finding cancer cases
  - Uses existing X-ray products (film or digital)
    - ~ 17,000 x-ray units currently installed in U.S. Hospitals
    - Standalone units for film
    - Easy connectivity to digital x-ray units
    - Cost - $150,000 per unit digital or film based

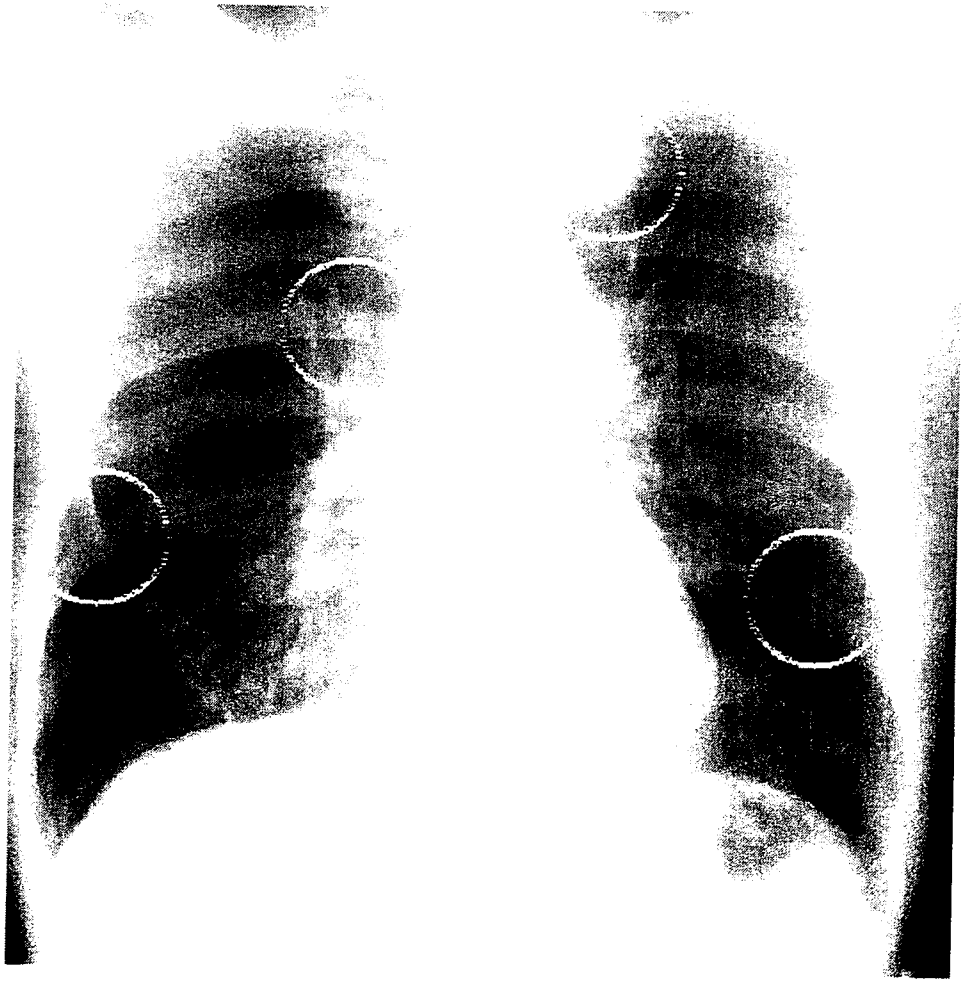
X-Ray CAD Improves Early Lung Cancer Detection

- Only 16% of lung cancers are detected in the early stage (American Cancer Society).
- X-Ray CAD results in 21% improved detection of early stage cancer when radiologist are specifically looking for cancer.
  - (Result from clinical study demonstrating effectiveness)

What is X-Ray CAD?

- Computer-aided detection (CAD) helps increase lung cancer case findings.
- Using routine chest x-rays, X-Ray CAD identifies regions of interest (suspected nodule sites) and circles them for further analysis by a radiologist.
- There is no additional radiation exposure for the patient because X-Ray CAD uses existing x-ray images.

Example of Typical Output of an X-Ray CAD Image



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Cover X-Ray CAD Now

- Early Detection Saves Lives
  - As many as 53,000 lung-cancer lives could be saved annually through early detection.
- Early Detection is Cost-Effective.
  - CAD uses X-rays already obtained.

AMA Approved CXR CAD CPT Code

- Approved AMA Category III CPT Code effective July 1, 2005 for Third Party Payer Chest CAD Radiography.

0152T Computer aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; chest radiograph(s) (List separately in addition to code for primary procedure)
(Use 0152T in conjunction with 71010, 71020, 71021, 71022, and 71030)

Next Steps

- Expedite Medicare Reimbursement Code for Chest X-Ray CAD?

William P. Truels, M.D., F.A.C.S.

GENERAL SURGERY
DEACONESS MEDICAL OFFICES
5701 N. PORTLAND, #120
OKLAHOMA CITY, OKLAHOMA 73112

TELEPHONE 951-4110
FAX 951-4111

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SEP - 2 2005

August 24, 2005

The Honorable Mark McClellen, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
Attention: CMS - 1501 - P
Post Office Box 8016
7500 Security Boulevard
Baltimore, MD 21244-8018

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule

File Code: CMS - 1501 - P
Proposed Payments for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Status

Dear Dr. McClellen:

As a part of my practice, I care for patients with chronic wounds and as such am extremely concerned with the proposed 2006 Medicare Hospital Outpatient payment rates for Apligraf [C 1305] and Dermagraft [C 9201]. For this reason, I am commenting on the Centers for Medicare and Medicaid Services [CMS] Proposed Rule - Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule.

Dermagraft and Apligraf are both living human tissue substitutes used to treat chronic wounds and are adversely impacted by the 2006 proposed payment rates.

Based on significant clinical evidence, both are FDA PMA approved and in use for more than five years. Apligraf and Dermagraft have

improved the quality of life of thousands of Medicare beneficiaries who suffer from chronic wounds. As demonstrated in clinical trials, many Medicare patients would have likely undergone amputations without the benefits of these products.

Dermagraft and Apligraf were paid as biologics since 2002 under the Hospital Outpatient transitional pass through program. With the passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, they have been paid as sole-source biologics in 2004 and 2005.

In the 2006 Medicare Hospital Outpatient proposed rule, CMS intends to reimburse specified covered outpatient drugs at average sales price [ASP] plus six percent for the acquisition cost of the drug.

For some reason however, in the proposed rule both Apligraf and Dermagraft were incorrectly paid based on 2004 claims data instead of payment based on ASP. Because of the claims data calculation, both products experienced a significant decrease in payment which is unacceptable for purchasing hospitals:

Medicare Hospital Outpatient

	2005 - Actual	**2006 - Proposed**
Apligraf [C 1305]	$ 1,130.88	**$ 766.84**
Dermagraft [C 9201]	$ 529.54	**$ 368.32**

Dermagraft and Apligraf have been reimbursed in the hospital outpatient setting as covered outpatient drugs and this payment methodology should continue in 2006 like other covered outpatient drugs. Without this, Medicare beneficiary access to these advance treatment options is jeopardized by the payment rates in the 2006 Medicare proposed rule.

I request that the proposed 2006 Medicare hospital outpatient reimbursement for Apligraf and Dermagraft be corrected in the final rule to be issued later this year.

Thank you for your prompt attention and correction of this issue.

Best regards,

WILLIAM P. TRUELS, M.D. F.A.C.S.
5701 N. PORTLAND, #120
OKLAHOMA CITY, OK 73112
(405) 951-4110

cc: Herb B. Kuhn
Director, Center for Medicare Management
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20201

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ISOSCAN, LLC.

949 N. Curtis Road

Boise, ID 83706

Burley
Kane
Snow
Hart
Brzell

The Honorable Mark McClellan
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

ATTN: FILE CODE CMS-1501-P

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and calendar year 2006 Payment Rates

Dear Dr. McClellan:

I am writing on behalf of the seven hospitals in the Northwest that we service with mobile PET/CT on an issue of great importance to Medicare beneficiaries with cancer.

ISOSCAN is one of the leading mobile providers in the Northwest for cancer care. Positron emission tomography (PET) technology scans are an integral part of the rural imaging program to diagnose and manage patients with cancer. We are pleased that the Centers for Medicare and Medicaid Services (CMS) has recently proposed to expand cancer coverage for PET scans. We are concerned, however, that the proposed hospital outpatient payment rate for PET/CT scans is inadequate to cover hospital costs for this new technology. As reported previously to CMS, our cost average approximately $1485 that covers FDG, mobile mileage to sites, technologists, supplies, equipment maintenance, scheduling and other required items to provide safe and effective treatment.

Last year's reduction, meant that several hospitals in our service area could no longer provide this type of patient care. Patients at these sites now either do not receive a PET/CT, and thus adequate care, or have to drive in many cases over 150 miles to a major city location. Providing care in the Western states where population density is less, mileage between cities is more, and the cost of doing business is higher is extremely challenging now and further cuts will directly result in lack of patient services being delivered.

The PET/CT scanner is the latest advance in oncology imaging which combines two state-of-the-art imaging modalities. PET is a highly sensitive technique that detects the metabolic signal from actively growing cancer cells in the body. The key to PET's effectiveness is that it provides physicians with information about the body's chemistry, cell function, and metabolism that anatomic imaging modalities such as CT and MRI are unable to provide. The PET scan does not provide the exact anatomic location of the signal in the body.

CT provides high-resolution anatomic information regarding the location, size, and shape of various lesions, however it cannot differentiate cancerous lesions from normal structures with the same accuracy as PET. The combined PET/CT scanner merges PET and CT images together, thereby more accurately identifying and localizing tumors in the body. This accurately has proven that it reduces overall patient treatment costs and avoids excessive restaging of cases.

Last year, CMS in the Hospital Outpatient Rule decreased payment rates for PET scans from $1375 to $1150. This decreased rate has challenged our ability to provide PET scans to medical beneficiaries as mentioned above. We applaud the CMS decision in proposed rule to keep stable the payment rate for PET scans, thereby avoiding further constraints on providers' ability to offer this service.

We are concerned, however, about the proposed payment rate for PET/CT. The PET/CT scan is the leading diagnostic imaging tool for managing patients with cancer. The proposed payment rate of $1250 is well below our cost for these scans. Without adequate reimbursement, beneficiary access to PET/CT will be limited, CMS may incur higher costs because of poorer treatment planning capabilities without PET/CT, and the threat of even lower rates in 2007 will stop investment in new technology as hospitals cannot continue to provide services at a loss without the ability to ever breakeven.

I urge you to keep the hospital outpatient payment rates for PET scans stable and to increase the payment rate for PET/CT to represent true costs for hospitals. Even consideration of a geographic adjustment factor would assist to ensure Western state beneficiaries at not left out by draconic cuts in reimbursement for PET/CT.

Thank you very much for considering the difficulty of continuing to provide services in such uncertain times. Please feel free to contact me with more information.

Very truly yours,

Jack Floyd, CEO
ISOSCAN, LLC.

MO

PHP Asplen Kane Sanow Hart Bazell

Woodcrest Healthcare, Inc Community Mental Health Center
Community Mental Health Center
PO Box 442
Natchitoches, La. 71457

8-17-05

File code: CMS-1501-P Partial Hospitalization
Re: Comment to CMS-1501-P Changes to Hospital Outpatient Prospective Payment System and calendar year 2006 Payment Rates-Proposed Rule

Our agency Woodcrest Healthcare, Inc. is a freestanding community mental health center in rural Natchitoches, Louisiana. We serve approximately _415_____ patients on an annual basis. We employ approximately 12 employees and contract workers in our community. We provide intensive psychiatric programs that are much needed by the patients in our community.

We have patients in our Partial Program who would require in patient psychiatric hospitalization if they did not attend the PP.

We are requesting the proposed 15% cut for our program be stopped. The current payment rate is not sufficient to cover the costs needed for our intensive programs. Our costs are higher than hospitals that can share and spread their costs to other departments. Our patient acuity level is also more intense than the hospital patients receiving one or two therapy sessions on Monday-Friday and none over the weekend.

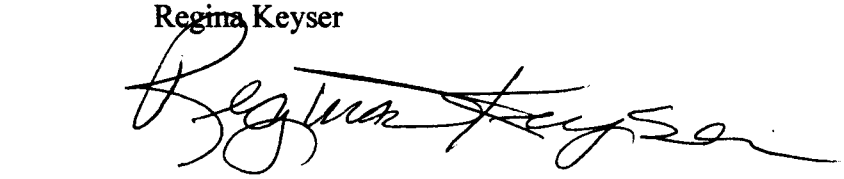
The service is especially needed for our rural community who are not serviced by hospital programs. Additionally our state does not offer this program as a Medicaid service.

Please consider not cutting the Partial Hospitalization Program cost so drastically when most outpatient costs are receiving a 3.5 % increase in payment rates.

We are going to be forced to close if we do not receive an increase in payment rates.

Sincerely.

Regina Keyser



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